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(54) Title: SUSPENSION PLATE FOR ATTACHING THE TEMPORALIS MUSCLE SUPPORTING SUTURES AND TO HOLD BONE FLAP IN ITS CORRECT ANATOMICAL POSITION

(57) Abstract: A temporalis suspension plate used after brain surgery for repositioning a skull fragment removed by a craniotomy prior to the brain surgery. The fragment is repositioned and held by the suspension plate in a predetermined position in the cranial aperture created by the craniotomy. The suspension plate includes a plurality of inner holes intermixed diagonally, and flexibly coupled, to a plurality of outer holes. The coupling may be by arms connecting the holes. The holes may be coupled to eyelet holes for receiving sutures.

SUSPENSION PLATE FOR ATTACHING THE TEMPORALIS MUSCLE SUPPORTING SUTURES AND TO HOLD BONE FLAP IN ITS CORRECT ANATOMICAL POSITION

BACKGROUND OF THE INVENTION

[0001] *Field of Invention*: The present invention relates generally to a suspension plate and, more particularly, to a temporalis suspension plate for easily attaching the sutures to attach the temporalis muscle and to hold the bone flap in its correct anatomical position.

[0002] *Description of the Related Art*: Neurosurgery surgical access to the brain is typically achieved by a procedure called "craniotomy" in which a piece of the skull or "bone flap" is cut out and removed to gain access to the brain. After surgery to the brain is complete this cut piece of bone or bone flap is repositioned in its correct anatomical location and fixed to the adjacent skull with small bone plates and screws. These plates and screws can be made of metallic materials such as titanium and titanium alloys or specialized plastic materials that dissolve or "resorb" away in the body over time. Plates typically consist of two or more round screw receiving receptacles or holes connected by one or more bridging connecting bars. The bar or bars bridge across the craniotomy cut and the screws are placed in the bone through the receptacle holes on each side of the cut to provide fixation. Three or more bone plates spaced roughly in equal distance around the bone flap provide stable fixation of the flap to the adjacent skull.

[0003] Additionally there are several muscles that are attached or anchored to the skull. Most notable of these muscles are the temporalis muscles located on each side of the skull, which are muscles of mastication or chewing. These muscles attach to the skull in the temporal regions in a broad area above the ears and at their other ends to the mandible or lower jaw. When a craniotomy is performed in the temporal region of the skull in areas covered by the temporalis muscle this muscle must first be cut loose or "elevated" from its attachment points and pushed aside to expose the bone where the craniotomy is to be made. After the completion of the brain surgery procedure, the craniotomy bone flap is repositioned and fixed in place. Likewise, the elevated temporalis muscle needs to be repositioned in its correct anatomical location as well. Various approaches are typically used to deal with the repositioned temporalis muscle at this point in the surgical procedure.

[0004] One method is to simply reposition the temporalis muscle in its correct anatomical position and close the scalp over the top of the temporalis muscle to complete the surgery. One of the drawbacks to this approach is that the upper or "superior" aspect of the temporalis muscle may easily migrate to an "inferior" or lower position as the muscles contract after the patient returns to consciousness or particularly as the patient chews food or simply swallows as both actions result in contraction of these muscles. This malpositioning of the superior part of this muscle has significant consequences as it can adversely effect the patients ability to chew with full effectiveness or in a balanced way as these are paired muscles working in concert on both sides of the head.

[0005] Besides malpositioning of the superior part of the temporalis muscle, a cosmetic deformity may also result in the form of an unnatural appearing hollow where the superior aspect of the muscles would normally be positioned and/or an unnatural bulkiness in the region of the more inferior part of the muscle. Moreover, because of the inferior malpositioning, the muscle may become non-functional or marginally functional resulting in atrophy and pain of the muscle and increased cosmetic deformity.

[0006] Other techniques employed to address the aforementioned problems involve the use of sutures passed through the muscle at several points which are then attached either directly to the skull through holes drilled in the bone or attached to the bone plates or screws used to achieve the bone fixation. These sutures provide temporary support of the muscle in its correct anatomical position until such time as biologic reattachment of the muscle to the bone occurs as a result of normal healing. The bone plates and screws, however, are not designed specifically to provide for attachment of sutures thus resulting in the possibility of the suture slipping along the connecting bar of the plate or slipping over the head in the case of suture fixation using a bone screw. Moreover, The other method whereby the sutures are anchored through holes drilled through the bone is less than optimal because it requires drilling the bone at a very shallow angle along the edge of the craniotomy cut.

[0007] Therefore, there still is a need for an apparatus and method for reattaching the temporalis muscle and holding the bone flap in its correct anatomical position.

BRIEF SUMMARY OF THE INVENTION

[0008] One aspect of the present invention is to provide a device that allows for easy attachment for the temporalis muscle supporting sutures while at the same time functioning as a bone fixation device to hold the bone flap in its correct anatomical position. This may be accomplished through a specially configured bone plate device that includes a suture eyelet hole, ring, and/or bar that allows for passage and fixation of a suture. Furthermore, fixation of the bone flap is facilitated by providing a bone plate device that includes an array of screw-receiving holes connected in series by bone plate connecting bar members with each connecting bar attachment angled relative to the screw-receiving holes such that the holes are offset from their adjacent holes by an amount suitable for bridging alternate sides of the craniotomy cut thereby providing for fixation of the bone flap.

[0009] Alternatively, the temporalis suspension plate may also be used for reconnection of the temporalis bone to the cranium, while not serving to affix the craniotomy bone flap to the skull. In this application, it would be applied directly to the bone flap, or the intact skull with screws as described to allow temporalis muscle reconstruction to its anatomic position.

[00010] Additionally, the connecting bar attachment points are angled such that any three or more alternate holes have a common centerline that forms an arc approximating the arc that typically defines the edge of a craniotomy cut. Thus the device may offer a close fit with the typical craniotomy cut with minimal re-shaping. If the subject device is supplied in some malleable material, such as titanium for example, the operating surgeon can easily accomplish re-shaping to fit the exact curve of the craniotomy cut. Alternatively, the muscle suspension plate may also be used elsewhere on the cranium, to reattach the occipitalis muscle, or other muscles with attach or insert upon the skull.

[00011] The above described and many other features and attendant advantages of the present invention will become apparent from a consideration of the following detailed description when considered in conjunction with the accompanying drawings.

[00012] BRIEF DESCRIPTION OF THE DRAWINGS

[00013] Detailed description of the preferred embodiment of the invention will be made with reference to the accompanying drawings.

[00014] FIG. 1 is an exemplary view of a temporalis suspension plate according to one embodiment of the present invention holding a bone flap in its correct anatomical position within a craniotomy cut in a skull;

[00015] FIG. 2A is a top view of the exemplary temporalis suspension plate according to FIG. 1;

[00016] FIG. 2B is an bottom view of the exemplary temporalis suspension plate according to FIG. 1;

[00017] FIG. 2C is a cross-sectional view of the exemplary temporalis suspension plate along the line 2C-2C in FIG.2A;

[00018] FIG. 2D is a cross-sectional view of the exemplary temporalis suspension plate along the line 2D-2D in FIG.2A;

[00019] FIG. 2E is a cross-sectional view of an another embodiment of a temporalis suspension plate;

[00020] FIG. 2F is a cross-sectional view of an another embodiment of a temporalis suspension plate;

[00021] FIG. 3 is a top view of yet another embodiment of a temporalis suspension plate;

[00022] FIG. 4 is a top view of still another embodiment of a temporalis suspension plate; and

[00023] FIG. 5 is a top view of yet another embodiment of a temporalis suspension plate.

DETAILED DESCRIPTION OF THE INVENTION

[00024] This description is not to be taken in a limiting sense, but is made merely for the purpose of illustrating the general principles of the invention. The section titles and overall organization of the present detailed description are for the purpose of convenience only and are not intended to limit the present invention.

[00025] FIG. 1 illustrates by way of example a suspension plate 10 in accordance with one embodiment of the present invention used to reattach the temporalis muscle and to hold the bone flap 12 in its correct anatomical position. Note that FIG. 1 shows the top view of the

suspension plate 10. Once a surgeon is done with the neurosurgery the bone flap 12 is repositioned into the craniotomy cut 14. To securely hold the bone flap 12 in its position, the suspension plate 10 is laid across the bone flap 12 and the skull 16. To couple the bone flap 12 to the skull, screws are inserted into a predetermined number of outer holes 18 and a predetermined number of inner holes 18' that are diagonal to each other. Moreover, a predetermined number of eyelet holes 20 are provided adjacent to the inner holes 18' so that sutures may be tied through the eyelet holes 20 that ties to the temporalis muscle.

[00026] FIGS. 2A-2D illustrate by way of example more detail views of the suspension plate 10. In this embodiment, the outer holes 18 and the inner holes 18' are coupled in series by arm members 22 that are diagonal to each other. The angel between the two adjacent arm member 22 is about 90. Accordingly, the inner holes 18' form an arc 24' in reference to a focal point 24; likewise, the outer holes 18 form an arc 24'' in reference to the same focal point 24; and, the eyelet holes 20 form an arc 24''' in reference to the focal point 24 as well. The suspension plate 10 may be arced to approximate the arc cut out portion 14' (FIG. 1) that typically define the edge of the craniotomy cut 14. That is, as illustrated in FIG. 1, the arc cut out portion 14' generally run between the two arcs 24' and 24''. This way, when a bone screw is inserted in to a predetermined number of outer holes 18 and inner holes 18' the bone flap 12 is securely held within the craniotomy cut 14.

[00027] Besides holding the bone flap 12 in its correct anatomical position, the suspension plate 10 also has the eyelet holes 20 adjacent to the inner holes 18' so that the sutures that reattach the temporalis muscle can be attached to the eyelet holes 20. In other words, the suspension plate 10 is generally positioned so that the inner holes 18' are facing the temporalis muscle as shown in FIG. 1. And the sutures 26 are used to attach the temporalis muscle to the eyelet holes 20. This way, the temporalis muscle is held in its correct anatomical position until the biological reattachment of muscle to the skull occurs as a result of normal healing. Incidentally, the outer edges of the temporalis muscle is arced as well so that the arc of the suspension plate 10 helps to attach the sutures between the eyelet holes 20 and the edges of the temporalis muscle.

[00028] With regard to material, the suspension plate 10 may be made of malleable material so that an operating surgeon can easily re-shape the suspension plate 10 to fit the outline of the craniotomy cut portion 14' and the curvature of the skull 16. That is, the angel between the two arm members 22 may be varied by the surgeon so that the craniotomy cut portion 14'

is between the outer holes 18 and inner holes 18' of the suspension plate 10. For example, suspension plate 10 may be made of titanium, which is malleable. Other materials such as stainless steel, other metals, biologic materials such as bone or coral, and resorbable or non-resorbable plastic or acrylic may be used as well. Of course, the suspension plate 10 may be made of any material known to one skilled in the art.

[00029] FIG. 2B illustrates by way of example a bottom view of the suspension plate 10 that is substantially flat. FIG. 2C illustrates by way of example a cross-sectional view an exemplary inner hole 18' and eyelet hole 20, along the line 2C-2C in FIG 2A. FIG. 2C shows the combination of holes 18' and 20 having a top surface 28 and a bottom surface 30. That is, the bottom surface 30 is placed over the skull so that the top surface 28 is facing up when implanting the suspension plate 10. Moreover, the inner hole 18' has a countersink 32 so that the head of a bone screw is more flushed with the top surface 28 once the bone screw is inserted into the inner hole 18'. The diameter of the inner holes 18 ' generally depends the diameter of the bone screw that is used. An exemplary diameter along the top surface 28 of the inner hole 18' may be about 1.5 mm to about 3.5 mm; and exemplary diameter along the bottom surface 30 of the inner hole 18' may be about 1.0 mm to about 2.5 mm. And the thickness t of the suspension plate 10 may be about 0.2 mm to about 1.0 mm. Of course, the thickness t of the suspension plate 10 may depend on the material that is used for the suspension plate 10, so that the suspension plate 10 is sufficiently flexible to be reshaped to match the craniotomy cut portion 14' and the curvature of the skull 16.

[00030] Moreover, as illustrated by way of example in FIG. 2A, an exemplary radius R1 that defines the arc 24''' of the eyelet holes from the focal point 24 may be about 4.0 cm to about 5.5 cm; an exemplary radius R2 that defines the arc 24' of the inner holes 18' from the focal point 24 may be about 4.5 cm to about 6.0 cm; and an exemplary radius R3 (see FIG. 2B) that defines the arc 24'' may be about 5.0 cm to about 6.5 cm. In particular, one embodiment of the suspension plate 10 may have the following radius dimensions: R1 at about 4.8 cm; R2 at about 5.0cm; and R3 at about 5.72 cm. Furthermore, as shown in FIG. 2B, the angel 2 between the outer hole 18 and inner hole 18' may be about 5.5 to about 6.5; and the angel 3 between the two outer holes 18 may be about 10 to about 14. In particular, in this embodiment, the suspension plate 10 may have the angel 2 at about 6, and the angel 3 at about 12 . Note that the above dimensions of the holes and angels may be other than dimensions discussed above.

[00031] FIG. 2D illustrates by way of example the cross-sectional view of the outer hole 18, along the line 2D-2D in FIG. 2A. The diameter and thickness of the outer hole 18 may be similar to the inner hole 18; however, they may be different. For example, the thickness t' of the outer hole 18 may be thinner than the thickness t of the inner hole 18', as further discussed below.

[00032] Alternative embodiment of the present invention is illustrated by way of example in FIG. 2E and 2F, a suspension plate 10' in this embodiment is symmetrical along the centerline C-C. That is, the top surface 28' and the bottom surface 30' are substantially similar to the top surface 28 shown in FIGS. 2C and 2D. One of the advantages with this embodiment is that the surgeon can place either surfaces 28' or 30' adjacent to the skull and still install a bone screw through the holes 18' and 18 and have the head of the bone screw be flushed within the countersink 32'. This way, a surgeon can not make a mistake of placing the wrong surface of the suspension plate 10 along the skull.

[00033] FIGS. 2G illustrate by way of example a cross-sectional view of the suspension plate 10 along the line 2G-2G in FIG. 2A, where thickness of the arm member 22 is substantially similar to thickness of the two holes 18 and 18'. Alternatively, FIG. 2H illustrates by way of example that the thickness t'' of the arm member 22' may be different from the two holes 18 and18'. That is, the thickness t'' may be thicker or thinner than the thickness t of the hole 18. For example, the holes 18 and 18' may be configured as in FIGS. 2E and 2F so that the thickness t of the holes is relatively thicker than the thickness t of the holes in FIG. 2C and 2D, but to maintain the flexibility or malleability of the suspension plate 10, the thickness of the arm member 22' may be thick as t in FIG. 2C and 2D.

[00034] FIG. 3 illustrates by way of example eyelet holes 20' and 20'' located in alternative positions. For example, the eyelet hole 20' is located along the interior side of the outer hole 18. That is, the eyelet hole 20' is further away from the temporalis muscle than the eyelet hole 20. This way, a surgeon may use the eyelet hole 20' to attach a suture to have more tension in the suture. Moreover, an eyelet 20'' may be placed along the arm member 22, which is between the eyelet holes 20 and 20'. The combination of holes 20, 20', and 20'' allows the surgeon to select the proper eyelet hole so that there is proper amount of tension in the suture.

[00035] Also shown in FIG. 3 is an eyelet hook 34 that may be located in the interior side of the inner hole 18', arm member 22, and outer hole 18. One of the advantage with the eyelet hook 34 is that the suture does not have to be passed through the eyelet hole 20; rather the suture may be simply "hooked" onto the hook 34, which saves time in reattaching the temporalis muscle. FIG. 3 also shows an elongated hole 36 where the inner hole 18' is combined with the eyelet hole 20. The elongated hole 36 may be placed along the arm member 22 and outer hole 18, as well.

[00036] FIG. 4 illustrate by way of example yet another embodiment of the present invention showing a suspension plate 10'' with the outer holes 18 and inner holes 18' but without the eyelet holes 20. In this embodiment, the outer holes 18 and the inner holes 18' may be used to attach the sutures. That is, in some instances, not every holes 18 and 18' may be used so that the holes 18 and 18' that are not used may be used to attach the sutures. Such holes might also be used for temporalis muscle reattachment and cranial fixation, simultaneously.

[00037] FIG. 5 illustrate by way of example still another embodiment of a suspension plate 10''' including the outer holes 18, inner holes 18', and the eyelet holes 20, as discussed above. In this embodiment, however, each of the outer holes 18 is coupled to its respective inner holes 18' via a tangential arm 38; and each of the tangential arm 38 are coupled by an arm member 22'.

[00038] With regard to method of manufacturing the suspension plate 10, photochemical etching processing, laser cut and machining process, water jet cutting and machining process, and electrical discharge machining process may be used, or any other method known to one skilled in the art. Although the present invention has been described in terms of the preferred embodiment above, numerous modifications and/or additions to the above-described preferred embodiments would be readily apparent to one skilled in the art. With respect to the claims, it is applicant's intention that the claims not be interpreted in accordance with the sixth paragraph of 35 U.S.C. § 112 unless the term "means" is used followed by a functional statement.

What is claimed is:

1. A temporalis suspension plate, comprising:

a plurality of inner holes;

a plurality of outer holes, wherein the plurality of outer holes are intermixed and diagonal to the plurality of inner holes; and

wherein the plurality of outer holes are flexibly coupled to the plurality of inner holes.

2. A temporalis suspension plate, comprising:

a plurality of holes, wherein adjacent holes are diagonal to each other defining an array of inner holes and an array of outer holes, wherein the adjacent holes are flexibly coupled to each other.

3. A temporalis suspension plate according to claim 2, wherein a predetermined number of inner holes has an eyelet hole.

4. A temporalis suspension plate according to claim 2, wherein a predetermined number of outer holes has an eyelet hole.

5. A temporalis suspension plate according to claim 2, wherein a predetermined number of inner holes has an eyelet hook.

6. A temporalis suspension plate according to claim 2, wherein a predetermined number of outer holes has an eyelet hook.

7. A temporalis suspension plate according to claim 2, wherein a predetermined number of inner holes are elongated holes.

8. A temporalis suspension plate according to claim 2, wherein the array of inner holes form an arc.

9. A temporalis suspension plate according to claim 8, wherein the arc is defined by a radius from a focal point, wherein the radius is about 4.5 cm to about 6.0 cm.

10. A temporalis suspension plate according to claim 9, wherein the angel between the two outer holes in reference to the focal point is about 10° to about 14°.

11. A temporalis suspension plate according to claim 9, wherein the angel between the outer hole and an adjacent inner hole in reference to the focal point is about 5.5°

to about 6.5°.

12. A temporalis suspension plate according to claim 9, wherein the array of outer holes define an outer arc defined by an outer radius from the focal point, wherein the second radius is about 5.0 cm to about 6.5 cm.

13. A temporalis suspension plate according to claim 2, wherein the adjacent holes are coupled by an arm.

14. A temporalis suspension plate according to claim 13, wherein the adjacent arms are about 90° apart.

15. A temporalis suspension plate according to claim 2, wherein the temporalis suspension plate has a top surface and a bottom surface, wherein the top surface and the bottom surface are symmetrical.

16. A temporalis suspension plate according to claim 2, wherein the temporalis suspension plate is made of titanium.

17. A temporalis suspension plate, comprising:

a predetermined number of pair of inner and outer holes; and

a flexibly arm coupling each of the predetermined number of pair of inner and outer holes.

18. A temporalis suspension plate according to claim 17, wherein each of the inner holes is coupled to an eyelet hole, wherein the eyelet hole is adapted to receive a suture.

FIG. 1

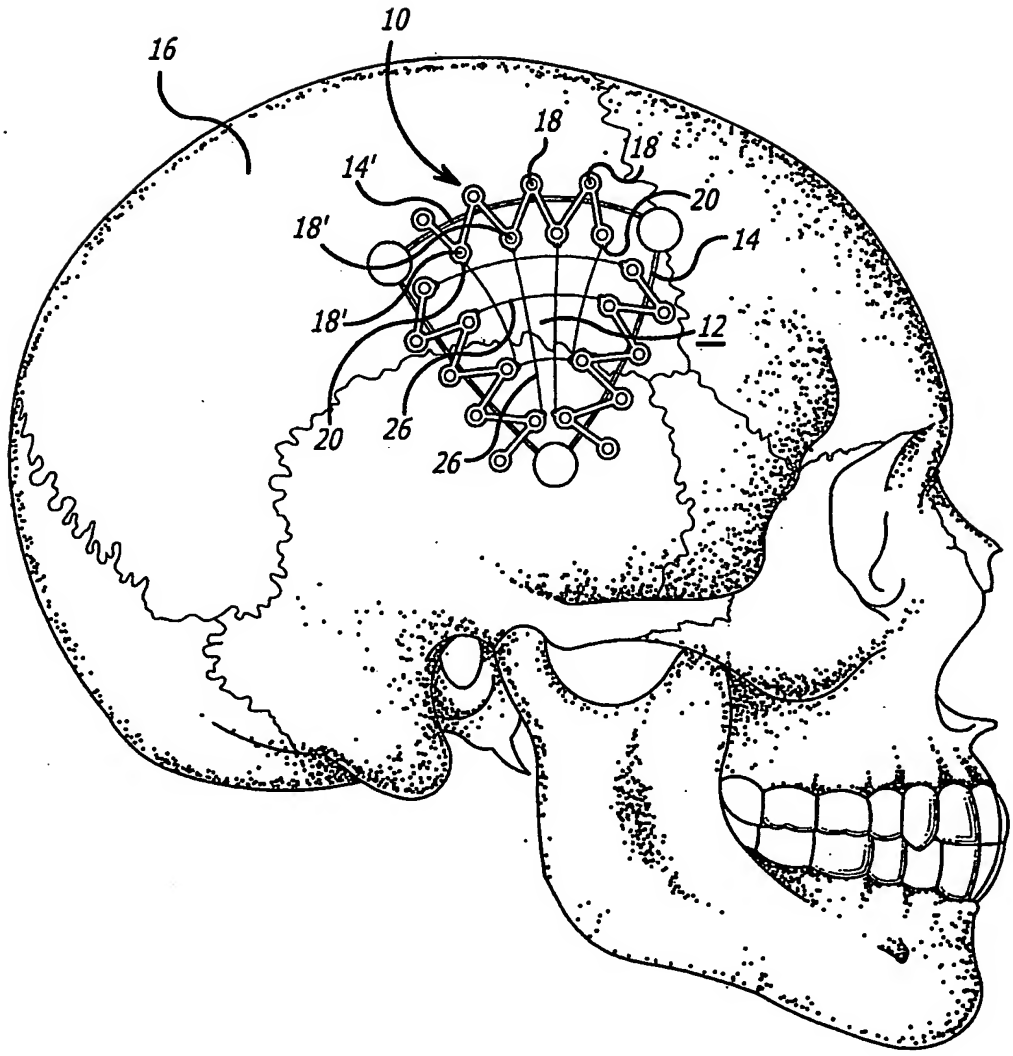
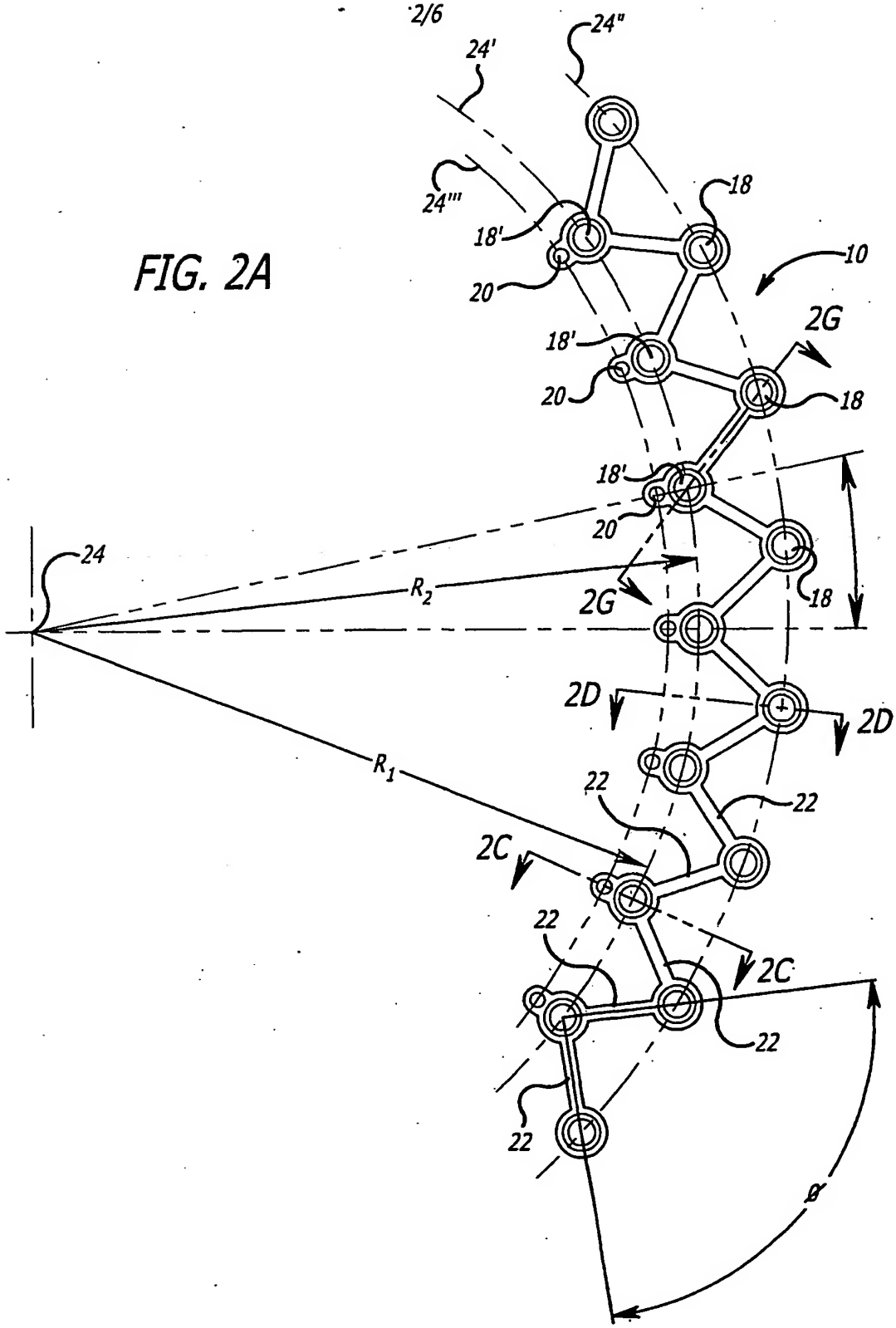


FIG. 2A


24'
24"
24'''
18
18'
10
20
2G
18'
20
18
18'
20
24
R_2
2G
18
2D
2D
R_1
22
22
2C
22
2C
22
22
θ

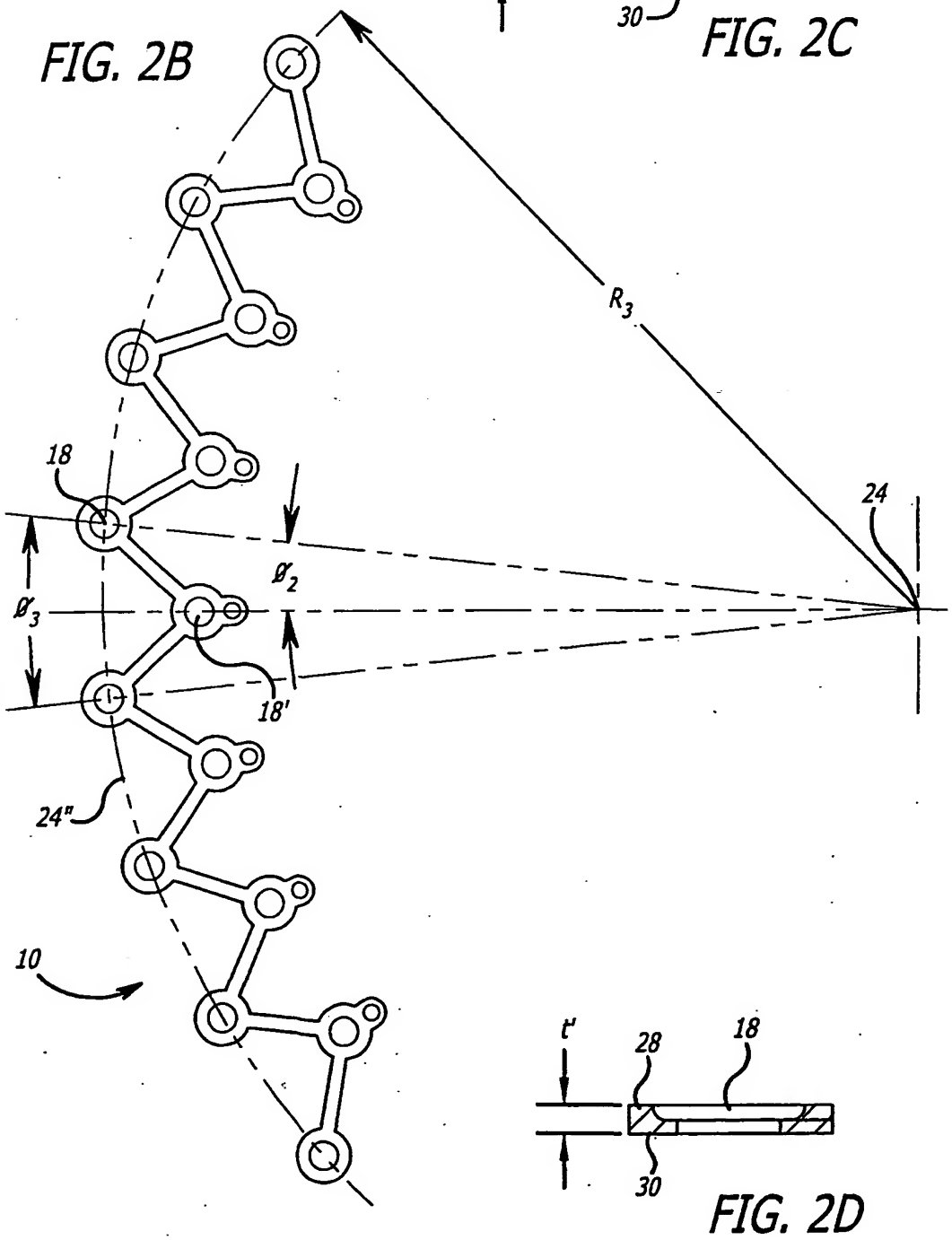


FIG. 2B
t
20
28
18'
32
30
FIG. 2C
R_3
18
24
$\emptyset_2$
$\emptyset_3$
18'
24"
10
t'
28
18
30
FIG. 2D

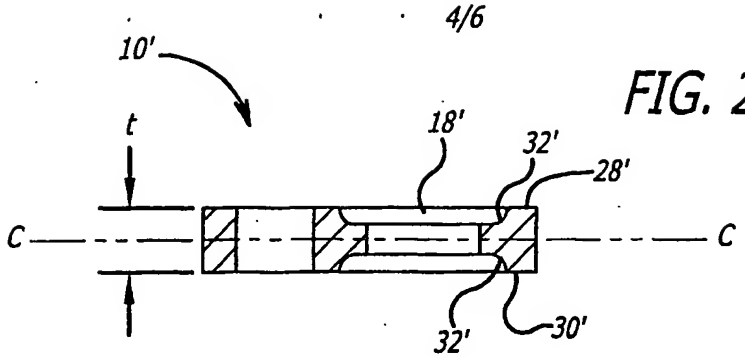


FIG. 2E

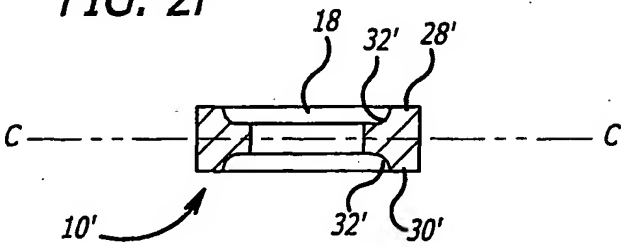


FIG. 2F

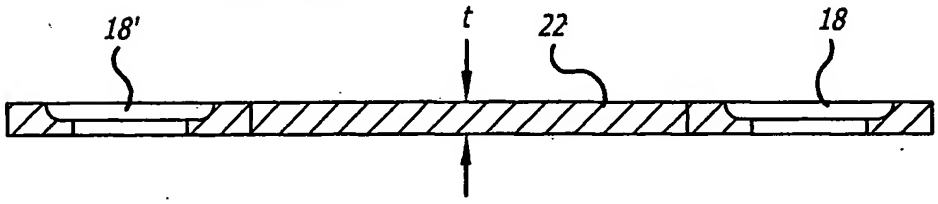


FIG. 2G

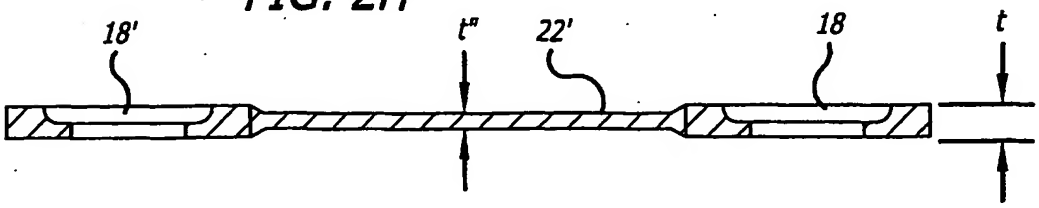


FIG. 2H

FIG. 3

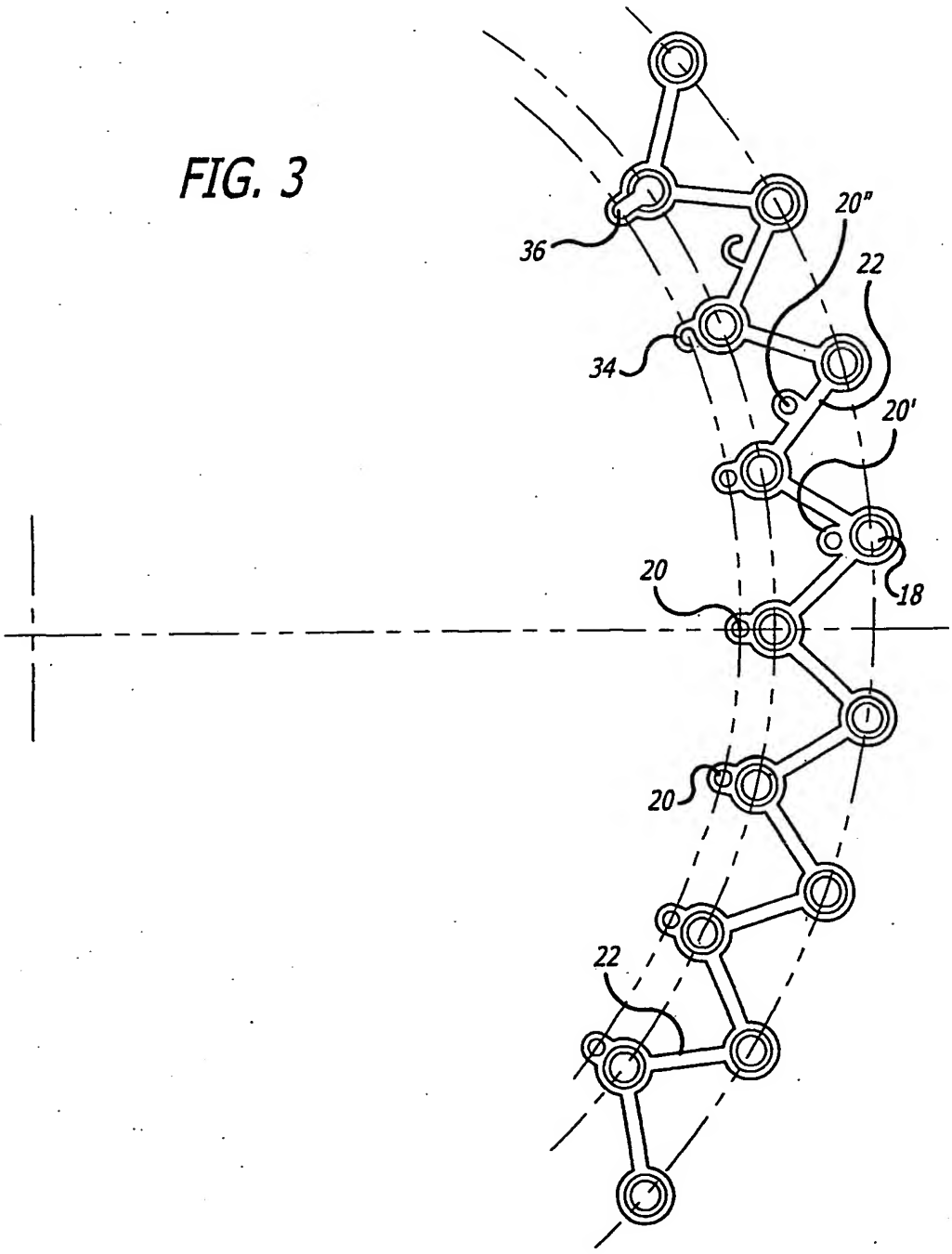


FIG. 4

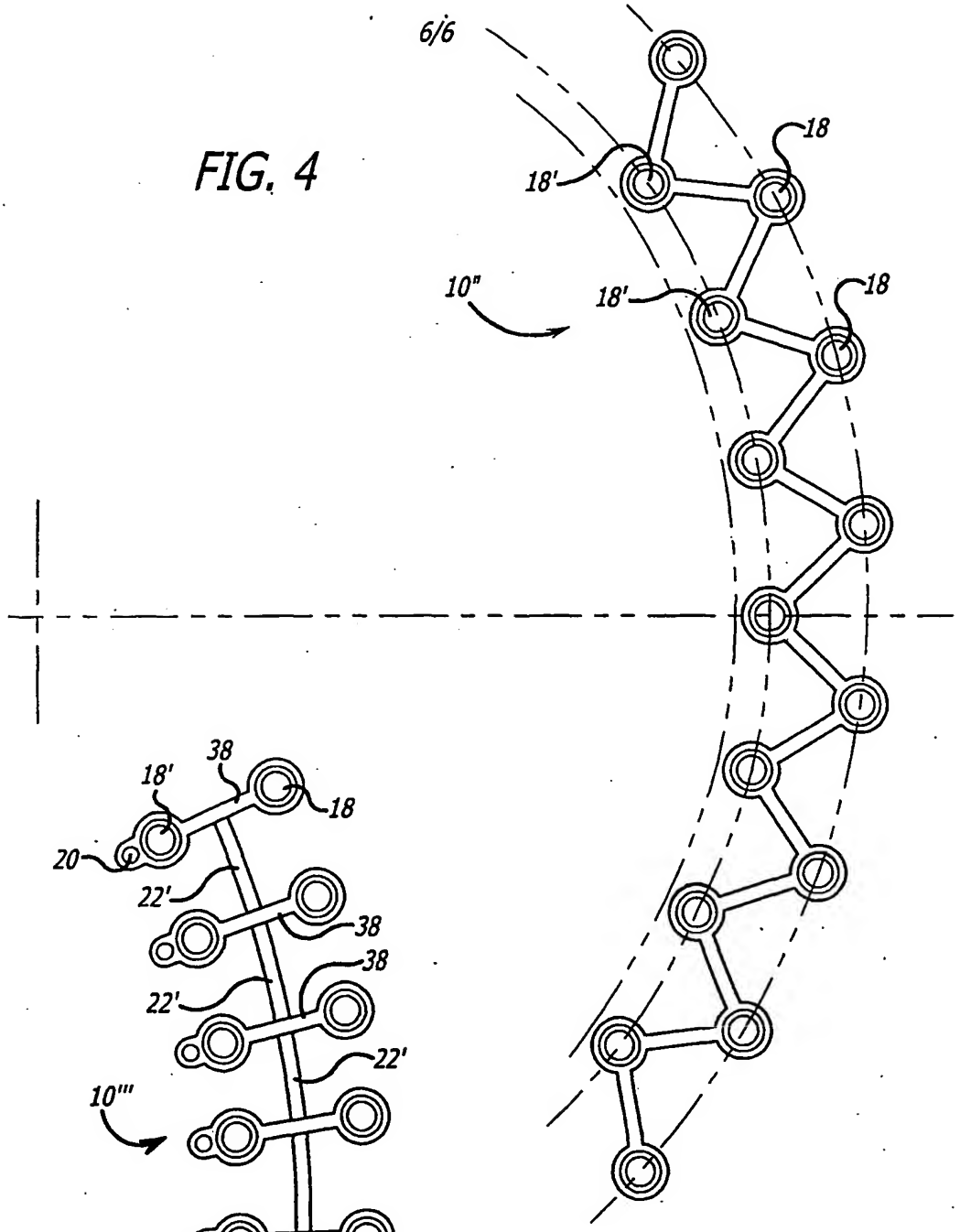


FIG. 5